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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,983	11/28/2000	Scott A. Waldman	TJU-2444	8378

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EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,983	WALDMAN, SCOTT A.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,28-30,36 and 50-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23, 28-30, 36, and 50-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Re: Waldman, S.

Date of priority: 10/26/1993

Response to Amendment

The Amendment filed 08-30-04 in response to the Office Action of 01/07/04 is acknowledged and has been entered.

Claims 58-80 were added. *(note: claim 57, was previously pending. Thus, its status as "new" was incorrect as presented by applicants on 08-03-04).*

Claims 23, 28-30, 36, and 50-80 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 23, 28-30, 36, and 50-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record and for the reasons set forth below.

Applicants argue (Remarks, 08-30-04) that none of the cited references (Jain, Dillman and Weiner) provide sufficient evidence that one skilled in the art would doubt the objective

truth of Applicant's assertion that the claimed invention is enabled (page 9). In particular, applicants argue that Weiner dispels any doubts suggested by Jain or Dillman and puts in proper context the issues raised in those references. Applicants proceed to point out several positive quotes in Weiner that underline some of the pros of monoclonal antibody therapy. Applicants further argue that antibody specificity (one of the concerns of Weiner) would not be of concern in this particular case because ST receptors are not normally expressed outside of the intestine/colon. Applicants further argue that at the present time numerous monoclonal antibody preparations have been approved by the FDA (bottom of page 10) including those listed on page 11 of applicants' remarks.

Applicants also argue that the standard for enablement is not whether all potential obstacles to clinical efficacy can be circumvented, but whether the claimed invention can be described in such a manner as to enable a skilled practitioner to achieve the disclosed result. Applicants go on to point out that side effects of HAMA including anaphylaxis might apply to any antibody similarly administered and that such side effects are not more indicative of a lack of operability of the antibody compared to side effects of chemical chemotherapeutic drugs. These arguments have been carefully considered but are not found persuasive. The Weiner reference, published in 1999, indeed reviews some of the more recent laboratory and clinical successes of antibody-based therapies. However, there is no indication in Weiner that monoclonal antibody therapy was conventional in the field of oncology at the time the present invention was filed (1993). As set forth previously, even as recently as 1999, Wiener still acknowledges the many problems inherent to antibody-based therapies. Furthermore, it is well recognized that the general treatment of advanced cancer (such as the claimed metastatic cancer)

is highly unpredictable, and applicants have failed to provide sufficient guidance and or objective evidence that is reasonably predictive of a skilled practitioner to "achieve" the claimed method. For example, although the ST receptor may be expressed by cancerous cells, there is no guidance on the quantity of anti-ST receptor antibodies required to achieve successful anti-cancer activity. Further, monoclonal antibody therapy is antigen-specific. And, unlike conventional chemotherapy, which is generally known to target all actively dividing cells, the monospecificity of antibody-based therapies is not conventional in the art for the treatment of cancer. Further, while several monoclonal antibodies have been approved by the FDA as applicant's have pointed out, the majority of these have not been designed to target solid tumors. Only one, Erbitux, a monoclonal antibody that targets the epidermal growth factor receptor on colon cancer cells is even remotely close to the presently claimed invention. Hence, it is not reasonable to generalize and parallel the success of a few particular monoclonal antibodies with the currently claimed invention because not all monoclonal antibodies are equivalent in specificity, efficacy, and pharmacological activity. Lastly, the arguments of counsel cannot take the place of evidence in the record. In re Schulze,346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 23, 28-30, 36, and 50-80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 9-10, 30-31, 55-56, 58 of U.S. Patent No. 5,879,656 ('656) for the reasons of record. Applicants have maintained their intentions to file a Terminal Disclaimer, yet none has been provided.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

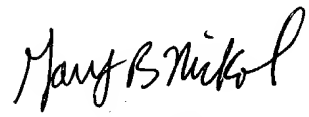
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN



GARY NICKOL
PRIMARY EXAMINER